

REMARKS

A. Summary of the Invention and Claim Amendments.

Claims 1, 12 and 34 are currently amended. After amendment, Claims 1-4, 8, 10, 12-16, 19, 21, 32 and 34-41 are pending.

The claimed invention provides the art with the discovery that fatty acid esters, such as isopropyl myristate, can be used to rapidly kill ectoparasites by itself; i.e., without application of other pediculocidal agents, such as alcohol (per the Singer reference) or insecticides.

The claims have been amended to address the objection to lack of antecedent basis in the Office Action as to Claim 16, so Claim 14 is now clearly drawn to use of the invention against ectoparasites, while Claim 16 is drawn to treating particular ectoparasites. The same general language being present in Claims 34 and its dependent claim 38, those claims have been amended in the same manner.

Claims 1, 12 and 34 have all also been amended for grammatical clarification. In particular, the word "alone" in the claims prior to amendment appears to have been read to qualify the immediately preceding word, ectoparasites. The amendments make clear that the word was to qualify the recitation of isopropyl myristate as the only active against ectoparasites present in an effective amount in the compositions used according to the invention.

No new matter being added to the Specification, entry of the proposed amendment is therefore requested. The Examiner's consideration of the claims as amended is appreciated.

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B. Response to Rejection under Section 112, Second Paragraph.

Claims 2-3, 13, 14, 35, and 36 are rejected for being indefinite and lack of antecedent basis. However, the only basis stated for the objection concerns Claims 14 and 16. As noted in the preceding section, that objection has been corrected by amendment.

Reconsideration and withdrawal of the objection is therefore respectfully requested.

C. Response to Rejection under Section 102, based on Singer

Claims 12-15 and 39-41 are rejected under Section 102, based on Singer, U.S. Patent No. 4,147,800.

The Office Action asserts that Singer teaches the use of isopropyl myristate (IPM) to kill ectoparasites at concentrations of 50 or 70%, and that it would have been obvious to one of ordinary skill in the art to omit alcohol from the Singer composition to avoid sensitivity thereto. Applicants respectfully submit that this is an inaccurate reading of Singer, for all of the following reasons.

1. According to Singer, an aliphatic alcohol is a critical component of the composition, and serves as an active agent against ectoparasites that must be provided with an ester compound. Singer explicitly *teaches away* from using any composition in which an aliphatic alcohol is not present:

[00007] **The pediculicidal toxicant of the instant invention is an admixture of an aliphatic alcohol and an aliphatic ester.** The combination is synergistic and retains its high level of activity when diluted in an inert pharmaceutically acceptable carrier, most notably an aqueous carrier.

[00010] The aliphatic esters exhibit good pediculicidal properties when applied in a substantially pure form, i.e., in a concentration of at least 70% or more. **Obviously,**

application of the esters in such a form is somewhat inconvenient and inappropriate. In the present invention, the ester is employed in an amount which is usually less than one half of the total toxicant composition employed. With respect to the total weight of the aliphatic alcohol and aliphatic ester, the weight ratio of the former to the latter is usually about 1.1:1 to 3:1 and preferably about 1.3:1 to 1.7:1.

[00012].... It has been found that **an effective pediculicidal toxic amount can be obtained when the amount of the aliphatic alcohol in the treating composition is at least about 20 percent by weight** and the amount of the aliphatic ester is at least about 15 percent by weight. Obviously, amounts of the alcohol and ester in excess of these minimum amounts can be employed but there appears to be no significant advantage if the percentages are significantly in excess of those stated.

In the claimed invention, NO alcohol or any other agent in an effective amount against ectoparasites is present in the composition. By requiring use of alcohol as an active agent, Singer unambiguously teaches away from the claimed invention.

2. Singer teaches that only IPM concentrations of 70% w/w are effective against ectoparasites, but that such concentrations cannot be used:

[00010] The aliphatic esters exhibit good pediculicidal properties when applied in a substantially pure form, i.e., in a concentration of at least 70% or more. **Obviously, application of the esters in such a form is somewhat inconvenient and inappropriate.**

In contrast, as indicated in Claims 39 and 40, Applicants have discovered that concentrations of IPM as low as 50% w/w are effective (in contradiction of Singer's contention that only concentrations in excess of 70% w/w are effective), and that concentrations as high as 100% w/w can be used (in contradiction of Singer's contention

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that such concentrations are “inappropriate”). By teaching (incorrectly) that esters can only be effective at concentrations that cannot be used, Singer unambiguously teaches away from the claimed invention.

3. According to Singer, a useful ectoparasiticidal composition of IPM is only obtained if an ectoparasiticidal amount of alcohol is present. Even then, nothing in Singer suggests that killing can be obtained within less than about 24 hours of application:

[00012] The **alcohol-ester admixture** is incorporated into the composition used to treat the substrate in need of such treatment, believed to be in need of such treatment, or desired to be prophylactically protected in an effective pediculicidal toxic amount. By such amount is meant the amount which will cause virtually 100% of the lice exposed in the two or four minute immersion test described below to die **within 24 hours**.

The present claims all require that the IPM kill at least 50% of ectoparasites within 10 minutes. This is a critical component of the claims, which is in no way taught or suggested by Singer.

For all of the above reasons, it is clear that Singer teaches away from the claimed invention by *requiring* use of an alcohol as an active agent. Singer further fails to teach or suggest the invention by teaching that even his alcohol/ester combination compositions do not kill ectoparasites within the time required by the present claims.

Reconsideration and withdrawal of the Section 102 rejection of Claims 12-15 and 39-41 are rejected under Section 102, based on Singer is therefore respectfully requested.

D. Response to Rejection under Section 103, based on Singer.

Claims 1-4, 32, 34-37, and 39-41 are rejected under Section 103, based on Singer.

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For all of the reasons stated above, Applicants respectfully submit that no one of ordinary skill in the art would be motivated by Singer to omit his key active ingredient—alcohol—from the composition. Nor would someone of ordinary skill in the art have reason to suspect, based on Singer, that doing so would provide an effective composition which could be used on humans (in contradiction of Singer's explicit warning not to use an aliphatic ester as an active at the concentrations he teaches are effective). And certainly, the ordinarily skilled artisan would have no reason to suspect that, should he ignore all of Singer's teachings to the contrary and use IPM as an active anyway, that killing of ectoparasites could be achieved in not more than 10 minutes.

Reconsideration and withdrawal of the Section 103 rejection of Claims 1-4, 32, 34-37, and 39-41 based on Singer is therefore respectfully requested.

E. Response to Rejection under Section 103, based on Singer in view of Reid.

Claims 12-15, 32, and 39-41 are rejected under Section 103, based on Singer in view of Reid, U.S. Patent No. 5,972,987.

Reid is cited only for its teaching with respect to use of a comb. It does not cure any of the deficiencies of the Singer reference noted above.

Reconsideration and withdrawal of Claims 12-15, 32, and 39-41 are rejected under Section 103, based on Singer in view of Reid, is therefore respectfully requested.

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CONCLUSION

All of the pending claims (1-4, 8, 10, 12-16, 19, 21, 32 and 34-41) are believed to be in condition for allowance. Reconsideration of the claims rejections is therefore requested as outlined above.

No fees are believed to be due in connection with the filing of this paper. However, the Commissioner is hereby authorized to charge any other fees that may be due in connection with the filing of this paper, or credit any overpayment to Deposit Account No. 07-1896, referencing the above-identified docket number.

Respectfully submitted,

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